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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/140,886

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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/140,886

Applicant(s)

Wilson et al

Examiner

Fox

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/20/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' arguments in the response of 20 September 2002 have overcome the rejection under 35 USC 102 over Masoud et al.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 2 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 2-3 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the recitation of "uncharacterized" in claims 1 and 15, as stated on page 3 of the last office action.

Claims 1-2 and 8-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by EP 299,552 (SOLVAY), as stated on pages 3-4 of the last office action.

Claims 1, 4, 8 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Korohoda et al, as stated on page 4 of the last office action.

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Claims 1, 4, 6, 8, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al, as stated on pages 4-5 of the last office action.

Claims 1, 4, 6, 8, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Soyfer et al in light of Turbin et al, as stated on pages 5-6 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 299,552 (SOLVAY), as stated on pages 6-7 of the last office action.

No claim is allowed.

Applicant's arguments filed 20 September 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection and enablement rejections are improper, given the teachings of the Wilson and Stine declarations submitted on 20 February 2001. Applicant further argues that the absence of regulatory DNA on the uncharacterized DNA fragment will not result in the production of plants with improved agronomic characteristics (page 2 of the response, penultimate paragraph). Applicant also urges that the Holl et al and Kamra et al teachings have not been substantiated by subsequent workers.

The Examiner maintains that the Wilson declaration demonstrates the obtention of corn plants transformed with the uncharacterized sorghum DNA bounded by two selectable marker genes, as evidenced by the expression of those non-sorghum marker genes; while the Stine declaration merely opines that techniques are available for identifying and evaluating transformed plants and their progeny containing exogenous uncharacterized DNA and exhibiting improved

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agronomic traits. However, neither declaration demonstrates that the exemplified uncharacterized sorghum DNA actually conferred any trait, improved or otherwise, to the recipient maize plants.

Furthermore, neither declaration addresses the deficiencies set forth in the written description rejection, namely, that the specification does not adequately describe even the exemplified “uncharacterized DNA” from sorghum in terms of its sequence or genes present, that the specification does not identify any structural features of the “uncharacterized DNA” which would be responsible for its alleged (and unproven) function of conferring improved agronomic traits, and that the specification clearly does not demonstrate reduction to practice of any other “uncharacterized DNA” from any other donor plant species which would confer improved agronomic characteristics to a recipient plant. Given the single disclosure of an “uncharacterized DNA fragment” from a single plant species; the breadth of the claims which encompass any donor plant species from a multitude of unrelated species, genera, and families; and the lack of guidance as discussed above and previously; the specification does not provide an adequate written description of the genus as broadly claimed so that one skilled in the art would recognize Applicant to have been in possession of the claimed invention. See *University of California v. Lilly* cited previously.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*,

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119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products (i.e. the “uncharacterized DNA”), any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

As promised during the personal interview of 16 October 2002, the Examiner consulted his supervisor to investigate whether his interpretation of the Written Description Guidelines as applied to the instant claims was in accordance with the policy of Tech Center 1600. The Examiner’s supervisor confirmed that the Examiner’s position is consistent with current policy.

Regarding the enablement rejection, the Examiner maintains that the mere demonstration of integration of the “uncharacterized donor DNA” by the Wilson declaration does not remedy the unpredictability inherent in the expression of uncharacterized foreign DNA in cells of

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heterologous plant species, as set forth in previous Office actions. In addition, the unpredictability inherent in the maintenance of large stretches of “uncharacterized donor DNA” from heterologous or homologous species, when introduced into plants by a multitude of non-exemplified methods, as evidenced by Holl et al and Karma et al, has not been addressed by either declaration. The allegations of the Stine declaration are insufficient to overcome the evidence of unpredictability set forth by the Examiner in the form of scientific reasoning and publications. Applicant’s admission of this unpredictability, regarding the necessity of native regulatory sequences on the “uncharacterized DNA”, is noted above.

Regarding Applicant’s assertions that the results of Holl et al and Karma et al have not been substantiated by later workers, the Examiner disagrees. Holl et al and Karma et al demonstrated that large stretches of “uncharacterized DNA” were not maintained in plants into which they had been introduced. Other workers did not publish contrary results demonstrating success. If anything, subsequent workers’ silence on the matter only confirms the teachings of Holl et al and Karma et al that the technique remains inoperable. See also Applicant’s arguments on pages 4-5 of the response of 20 September 2002, traversing the prior art rejections newly set forth in the last office action, which arguments support the Examiner’s characterization of Holl et al and Karma et al.

Applicant urges that “uncharacterized” is not indefinite because it has an art-recognized meaning. The Examiner maintains that the specification is silent with respect to the definition of this term, and that no other evidence of its art-recognized definition has been presented. It is

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unclear whether the lack of characterization is with respect to complete sequence information, function or sequence of any putative protein or transcription product, sequence length, presence of restriction fragments or other domains or consensus sequences in an otherwise unsequenced piece of DNA, etc. Applicant's comments regarding "improved agronomic characteristics" are deemed moot in view of the failure of the Examiner to object to this term.

Applicant urges that the prior art rejections under 35 USC 102 or 103 over SOLVAY are improper, given the failure of the reference to teach or suggest "the use of uncharacterized DNA to generate transgenic plants for use in a breeding program" (page 4 of the response, top paragraph). The Examiner maintains that this intended use, merely recited in the preamble, is not given patentable weight. Every element of the body of the claims is taught by SOLVAY.

Applicant urges that all of the prior art rejections are improper, given the failure of the techniques employed therein to be reproduced or substantiated by subsequent workers, and the lack of molecular and genetic evidence presented by the references. The Examiner maintains that such an assertion is not probative. A declaration by a disinterested party attesting to the inoperability or lack of repeatability of the prior art methods would be more probative. In addition, Zhou et al do teach the use of molecular evidence, in the form of DNA probes, to demonstrate the incorporation of the uncharacterized DNA into the genome of the recipient plant (see, e.g., page 248, second paragraph).

Furthermore, the claims are not drawn to the stable, heritable maintenance of the "improved agronomic characteristics" over several generations (i.e. "genetic evidence"). The

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claims are also not drawn to the particular method of transformation utilized by Applicant to obtain stable integration of the uncharacterized DNA. The claims are also not drawn to the donor and recipient plant species utilized by Applicant to demonstrate unexpected results. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

November 26, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

